IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**MDL No. 1871** **07-md-01871-CMR**
THIS DOCUMENT RELATES TO ALL ACTIONS	

APRIL 2010 STATUS REPORT OF THE SPECIAL MASTER

Pretrial Order No. 8 authorizes the Special Master to file periodic status reports on the progress of activities overseen by the Special Master. This Status Report sets forth the progress of activities covering the past few months.

In the past few months, the Special Master has met in person with the parties on a number of occasions, including February 8, 2010, March 19, 2010 and April 1, 2010. In addition, the Special Master and the parties have held a number of telephonic conferences. Much progress has been made during each of these sessions in resolving the discovery disputes brought to the Special Master's attention, primarily due to the parties' willingness to compromise and work cooperatively with each other in resolving disputes. A brief summary of the various issues raised with the Special Master and their resolution is set forth below:

Document Production

Most of the discovery disputes during this period have involved document production issues. A description of some of the key disputes follows.

The PSC requested additional information from GSK's OCEANS database, specifically all versions of each report in the database. GSK objected that the parties already agreed on the production protocol, which only included the initial date of a report and the last version of the report, and that it would be prohibitively costly and disruptive to extract the requested information from the database. After numerous discussions between the parties, some of them with the assistance of the Special Master, the parties reached a resolution of this issue.

The PSC also requested that GSK produce the individual SAS datasets for seven of GSK's Avandia studies. The PSC contended that its experts needed this patient-level data to fully analyze the studies. GSK previously provided this data for the Integrated Clinical Trials and RECORD study, but argued that it was too burdensome to provide this data for the other studies, particularly given privacy concerns that would require extensive review and redaction of the data. After further submissions from the parties regarding the burden on GSK of producing such data, the Special Master recommended that GSK produce the requested data for three of the seven studies, with the PSC to identify the three studies for which it would receive the data.

The PSC sought to obtain GSK documents related to development of the new drug Darapladib. The PSC argued that this new drug is relevant to the present case because it is aimed at decreasing an enzyme (Lp-PLA2) that allegedly increases the risk of heart attacks and strokes, while Avandia allegedly increases the enzyme. GSK objected that it had already given the PSC all documents involving Avandia and Lp-PLA2, and it should not have to produce documents regarding an unrelated drug, Darapladib. The Special Master recommended that the PSC's request be denied. The PSC has not appealed this recommendation to the Court.

In order to identify which sales and marketing materials were used by each sales representative, PSC requested that two depositions be taken of regional managers in each case to ascertain which documents were actually used in the field. GSK objected and, after further discussion, the Special Master recommended that the PSC provide a list of sales materials to GSK, and GSK would identify which of the materials were actually used by sales representatives. The parties accepted this recommendation.

In September 2009, the Special Master approved a list of eleven third-party entities from which the PSC sought to obtain discovery. A few months later, the PSC served third-party subpoenas on additional entities not on that list. In early April 2010, GSK objected to these subpoenas on the grounds that they were inconsistent with the prior resolution of this issue and it was too late in the discovery process to be revisiting the issue. After reviewing the parties' submissions on this dispute, the Special Master denied GSK's specific request that the PSC not be permitted to serve these third-party subpoenas, but the Special Master further recommended that, before the PSC serves any additional third-party subpoenas in the future, it should seek permission in writing for such additional discovery from the Special Master, with an explanation of the need for such discovery and why it was not sought earlier. Neither party objected to this recommendation.

A number of other document production issues were amicably resolved with the assistance of the Special Master. For example, GSK had previously produced documents related to Avandastat, a combination of Avandia and a statin, but had redacted certain information in these documents. The PSC then requested unredacted versions of these documents. After much discussion, the parties resolved their dispute over this issue. The PSC also sought to obtain copies of GSK's standard operating procedures ("SOPs") related to Avandia regulatory and

pharmacovigilence matters. After GSK objected to the scope of this request, the PSC agreed to narrow its request to only 25 SOPs. The parties were then able to resolve their differences.

Deposition Issues

A number of disputes have arisen regarding the scheduling and length of depositions. Most of these disputes have been amicably resolved through mediation, although the Special Master has issued recommendations regarding certain disputes, including GSK's request for a second day of deposition for Dr. John Gueriguian; GSK's request for production of a deponent's custodial file; and a request to quash a deposition of a treating physician.

Privilege Issues

At the March and April 2010 conferences, the parties discussed GSK's progress in conducting its re-review of its documents withheld as privileged, in light of the Court's ruling in PTO No. 84, which adopted in substantial part the Special Master's recommendations regarding GSK's assertion of privilege for certain initial documents reviewed by the Special Master and the Court *in camera.*

Following the PSC's review of GSK's revised privilege log, the Special Master agreed to review *in camera* 100 documents withheld by GSK, as selected by the PSC. At the March 2010 conference, the Special Master discussed with the parties his recommendations regarding the 100 sample documents. With the consent of GSK, some of the sample documents were shared with the PSC, including those that the Special Master recommended be produced and those he recommended be withheld. The PSC agreed that a number of the withheld documents were properly withheld as privileged, but disagreed about others. Following the conference, the Special

Master notified the parties of his recommendations as to all 100 sample documents. Neither party objected to those recommendations.

Further discussions on this topic were held after the March 2010 conference, including at the April 2010 conference. The parties agreed that, as a next step, the PSC would review GSK's final privilege log after the re-review process was complete and then notify the Special Master whether it was satisfied that GSK has done everything reasonably possible to comply with the Court's privilege ruling and therefore, did not seek any further review by the Special Master. GSK has now produced its final privilege log and the parties have continued their discussions on this issue in an attempt to finally resolve the privilege dispute. The PSC will shortly inform the Special Master whether it has any further objections to GSK's privilege assertions, as reflected in its final privilege log.

Additional Issues

At the April 2010 conference, GSK expressed concern that 569 plaintiffs had not complied with PTO No. 86, which requires all plaintiffs to produce basic medical records to GSK. The PSC agreed to help coordinate efforts with individual plaintiffs' attorneys to get the required records produced. GSK also agreed that it will copy the PSC on letters to individual plaintiffs' lawyers noting the lack of compliance with PTO No. 86, so that the PSC can assist in ensuring that all plaintiffs comply with PTO No. 86.

An ongoing dispute has existed over the PSC's production of supplemental expert reports, long after the deadline for the PSC's submission of its expert reports. GSK has complained that, in some cases, the supplemental reports are based on documents that were in the PSC's possession long before the expert deadline. PSC has responded that its production of the

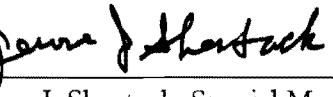
supplemental reports is justified on a number of grounds. The Special Master has recommended that no additional supplemental reports be served by either party, without prior approval of the Special Master upon good cause shown. Neither party objected to this recommendation.

A dispute also arose over GSK's request for medical records and independent medical examinations of a decedent's spouse and son who allegedly were claiming psychological injuries as a result of the decedent's death. After much discussion and the issuance of recommendations by the Special Master, the parties resolved these issues amicably.

Copies of this Status Report are being sent to counsel for the parties.

Respectfully submitted,

Dated: April 30, 2010



Jerome J. Shestack, Special Master

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CERTIFICATE OF SERVICE

I, Bruce P. Merenstein, hereby certify that on April 30, 2010, I caused to be electronically filed the foregoing **April 2010 Status Report of the Special Master**. Through the Court's ECF system, this document is available for viewing and downloading.

/s/ Bruce P. Merenstein
Bruce P. Merenstein